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Food and Agricultural Import Regulations and Standards

Sanitary and Epidemiological Norms and

Regulations–SanPin 2.3.2.1078-01

2002

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Report Highlights:

New food sanitary regulations have come into force in Russia. Post provides an informal translation of the table of contents and the regulation's scope, general provisions, and hygienic requirements for food safety and nutrition.

Includes PSD changes: No
Includes Trade Matrix: No
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Summary

New food safety regulations for the Russian Federation (SanPin 2.3.2.1078-01) entered into force on September 1, 2002. Post reported on the most significant changes, including mandatory labeling of some types of GMO products, in GAIN Report RS2020 sent on August 15, 2002. We are now providing the complete unofficial translation of the table of contents, as well as SanPin-01's scope, general provisions, and hygienic requirements for food safety and nutrition.

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SanPin-01 (General Requirements)

APPROVE

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The Russian Federation

First Deputy Minister of Healthcare of

The Russian Federation

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2.3.2 FOOD RAW MATERIALS AND FOODSTUFFS

HYGIENIC REQUIREMENTS FOR THE SAFETY AND NUTRITION OF FOODSTUFFS

SANITARY EPIDEMIOLOGICAL RULES AND REGULATIONS

SanPin 2.3.21078-01

I. SCOPE OF APPLICATION

- 1.1 Sanitary epidemiological rules and regulations “Hygienic requirements for the safety and nutrition of foodstuffs” (hereinafter referred to as Sanitary Rules) establish hygienic regulations for the safety and nutrition of foodstuffs in reference to human individuals as well as requirements with respect to compliance with the above regulations in foodstuff manufacturing, importation and distribution.
- 1.2 These Sanitary Rules have been developed based on the Federal Laws of the Russian Federation “On sanitary epidemiological well-being of the population” (Code of Laws of the Russian Federation, 1999, #14, Article 1650), “On quality and safety of foodstuffs” (Code of Laws of the Russian Federation, 2000, #2, Article 150), “On radiation safety of the population” (Code of Laws of the Russian Federation, 1996, #3, Article 141), “On protection of consumers’ rights” (Code of Laws of the Russian Federation, 1996, #3, Article 140), “The basic legislation of the Russian Federation on protecting citizens’ health” (News from the People’s Deputies Congress of the Russian Federation and the Supreme Council of the Russian Federation, 1993, #33, Article 13818), decrees of the Russian Federation Government of July 24, 2000 #554 “On approval of the Regulation of the State sanitary epidemiological service of the Russian Federation and the Regulation on the State sanitary epidemiological regulating” (Code of Laws of the Russian Federation, 2000, #31, Article 3295).
- 1.3 The Sanitary Rules are designed for citizens, individual entrepreneurs, legal entities involved in activities in the field of foodstuff manufacturing, importation and distribution; rendering services in foodstuff retail trade and in the public food catering chain, as well as for entities and institutions of the State Sanitary Epidemiological Service of the Russian Federation (hereinafter referred to as Gossanepidservice of Russia) engaged in the state sanitary epidemiological oversight and control.
- 1.4 Specific sanitary epidemiological rules and regulations establish hygienic requirements for the substances and materials that come into contact with foodstuffs.

II. GENERAL PROVISIONS

- 2.1 Foodstuffs shall satisfy physiological needs of human individuals for necessary substances and energy, comply with the requirements commonly requested from food products with regard to organoleptic and physical chemical properties, and meet the requirements approved by regulatory documentation with regard to permissible levels of chemical, radioactive, biological substances and their compounds, microorganisms and other biological organisms that present a threat to the health of the present and future generations.
- 2.2 Foodstuffs that are produced, imported and distributed on the territory of the Russian Federation shall comply with the Sanitary Rules with regard to safety and nutrition.
- 2.3 It is not allowed to produce, import and distribute foodstuffs which do not meet the requirements established by these Sanitary Rules.
- 2.4 The requirements of these Sanitary Rules shall be met for development of technical documentation regulating issues of foodstuff manufacturing, importation and distribution.
- 2.5 When developing new kinds of foodstuffs, new technological processes for their manufacturing, packaging, handling, and transportation, individual entrepreneurs and legal entities shall substantiate the requirements for the quality and safety, the quality and safety maintenance; develop programs for the production control over the quality and safety, testing methods, establish shelf life for such foodstuffs.
- 2.6 Drafts of technical documentation are subject to sanitary epidemiological evaluation in accordance with approved procedures.
- 2.7 Foodstuff manufacturing on the territory of the Russian Federation, or importation of foodstuffs into the territory of the Russian Federation for the first time is allowed only after state registration in accordance with the approved procedures is complete.
- 2.8 Imported foodstuffs are to be state registered prior to importation into the territory of the Russian Federation.
- 2.9 Foodstuff manufacturing is carried out in accordance with regulatory and technical requirements, and this is confirmed by the foodstuff quality and safety certificate (hereinafter referred to as the quality and safety certificate).
- 2.10 Foodstuffs manufactured in the public food catering system do not require the quality and safety certificate.
- 2.11 Foodstuff and technical requirement drafts are confirmed to be in compliance with the Sanitary Rules through sanitary epidemiological evaluation in accordance with the approved procedures.
- 2.12 If there are no safety and nutritional requirements in the Sanitary Rules pertaining to a specific new product or product imported for the first time, requirements are set for such product through sanitary epidemiological evaluation taking into consideration the following parameters:
 - the ones that are established by the developer of the new type of product in the proposed regulatory and/or technical documentation;
 - the ones that are established by the effective sanitary rules in reference to a product similar in composition and properties;
 - the ones claimed by the product in its country of origin;
 - the ones that are recommended by international organizations.
- 2.13 The requirements for foodstuff safety and nutrition are included in the sanitary epidemiological summary of the approved format that is issued by entities and institutions of the Gossanepidservice of Russia based on the results of sanitary epidemiological evaluation.

- 2.14 Food raw materials of plant origin require information pertaining to pesticides used during growing, fumigation of facilities and packages for storage, food supply pest prevention campaigns, and the date of the last treatment.
- Food raw materials of animal origin require information pertaining to the use (or non-use) of pesticides for the purpose of combating external parasites or animal and poultry diseases, treating livestock or poultry facilities, ponds and reservoirs for fish reproduction. It shall also include the name of the pesticide and the last date of its use.
- 2.15 It is prohibited to import, use and distribute food raw materials of plant or animal origin that do not have information pertaining to pesticides used in its manufacture.
- 2.16 Packaging of foodstuffs shall ensure preservation of quality and safety at all stages of product handling.
- 2.17 The individual entrepreneur and legal entity involved in activities pertaining to foodstuff manufacture and distribution, food service retail trade, and public food catering, shall provide the buyers and consumers as well as state oversight and control bodies with complete and accurate information with regard to the foodstuff quality and safety, the compliance with regulatory documentation requirements for foodstuff manufacturing and distribution and services in retail trade and public food catering.
- 2.18 Certain types of foodstuffs (products for children, dietary and specialized consumption, food additives, biologically active additives to food, foodstuffs produced with genetically modified sources (hereinafter referred to as GMO) and others) shall specify:
- the scope of application (for the products for children, dietary and specialized consumption, food additives, biologically active additives to food);
 - names of ingredients that are part of the foodstuff, food additives, microbial cultures, yeasts and substances used to enrich foodstuffs; biologically active additives to food and enriched products with biologically active components shall also include percentage of the daily physiological need, if such a need has been determined;
 - recommendations for usage, application, if necessary, contra-indications for their usage;
 - the information: “Is not a medicine” shall be necessary for biologically active additives to food;
 - the information: “genetically modified product”, or “product produced with genetically modified ingredients”, or “product contains components derived from genetically modified sources” (for foodstuffs that contain over 5% GMO components) shall be necessary for foodstuffs from genetically modified sources;
 - information on the state registration.
- Foodstuffs produced with GMOs and not containing deoxyribonucleic acid (DNA) and protein do not require additional labeling in cases where the product’s nutrition is completely equivalent to the traditional analog (Attachment 4).
- 2.19 The use of the terms “dietary”, “curative”, “prophylactic”, “baby food” or their equivalents in the names of foodstuffs in the information on a consumer package, and in the commercial sheets supplementary to the product are to be carried out in accordance with approved procedures.
- 2.20 When manufacturing animal origin food raw materials, it is prohibited to use feed additives, animal growth stimulants, medical drugs, pesticides (including pesticides for animal and poultry treatment, and preparations to treat facilities where they are kept) that have not been approved through state sanitary epidemiological evaluation and passed state registration in accordance with the approved procedures.
- 2.21 Food products containing feed additives, animal growth stimulants (including hormone preparations), medical drugs, pesticides, agricultural chemicals that have not been approved through

sanitary epidemiological evaluation and have not passed state registration in accordance with the approved procedures, shall not be imported, produced and distributed on the territory of the Russian Federation.

- 2.22 Production control and state sanitary epidemiological oversight and control are carried out over the compliance of foodstuffs with the safety and nutrition requirements.
- 2.23 Individual entrepreneurs and legal entities involved in foodstuff manufacturing, importation and distribution shall implement production controls, including lab research and testing, over the compliance of the foodstuff safety and nutrition parameters with the current Sanitary Rules requirements in accordance with the sanitary rules pertaining to organization and implementation of the production control.
- 2.24 Individual entrepreneurs and legal entities involved in foodstuff manufacturing and distribution shall issue a quality and safety certificate for every foodstuff shipment based on the results of the measures undertaken aimed at ensuring foodstuff quality and safety, and compliance with the regulatory and technical requirements, including production control implementation.
- 2.25 Individual entrepreneurs and legal entities involved in foodstuff manufacturing and distribution shall run lab research and tests independently or by engaging labs accredited in accordance with the approved procedures.
- 2.26 Metrologically certified procedures are allowed to control lab research and testing of foodstuff quality and safety. Those procedures shall meet requirements to ensure the consistency of measurements and the characteristics of measurement inaccuracies, kinds of usage during testing of produce samples and parameter control. Also, the procedures that meet the above requirements and have been accepted in accordance with the approved procedures are allowed.
- 2.27 Regulatory and technical requirements for culture medium designed to control microbiological parameters of foodstuff safety and nutrition are subject to sanitary epidemiological evaluation in accordance with approved procedures.
- 2.28 If test results prove to be unsatisfactory even in reference to at least one safety parameter, a double sized sample is tested repeatedly with the sample being taken from the same batch. The result of the repeated analyses shall refer to the whole batch.
- 2.29 The Gossanepidservice of Russia entities and institutions carry out the state sanitary epidemiological oversight and control over foodstuff compliance with the current Sanitary Rules in accordance with the approved procedures.

III. HYGIENIC REQUIREMENTS FOR THE FOODSTUFF QUALITY AND NUTRITION

- 3.1 These Sanitary Rules determine hygienic requirements for the safety of food products and their potential to satisfy physiological needs of human individuals in critical nutritional substances and energy.
- 3.2 Organoleptic properties of the food products are determined by the indices of taste, color, smell and consistency characteristic for each kind of product, and shall satisfy the traditional tastes and habits of the population. Organoleptic properties of the foodstuff produce shall not deteriorate during its storage, transportation and sale.
- 3.3 The food product shall not contain strange smells, tastes, and inclusions; it shall not differ in color and consistency from that characteristic for the given kind of product.
- 3.4 Foodstuff safety with respect to its microbiological and radiological characteristics, and to the content of its chemical contaminants shall be determined by the foodstuffs compliance with the hygienic

standards established by the current Sanitary Rules (Attachment 1).

- 3.5 Determination of foodstuff safety and nutrition for foods of mixed composition, including biologically active additives to food, is done in reference to the principal type(s) of raw material for both mass fraction and permissible levels of regulated contaminants.
- 3.6 Determination of safety parameters for dry, concentrated or soluble foodstuffs is done as converted to the initial product taking account of the dry substance content in the raw material and in the final product.
- 3.7 Hygienic regulations cover potentially hazardous chemical compounds and biological objects, the presence of which in foodstuffs shall not exceed the permissible levels in the tested mass (volume) of the given product.
- 3.8 Foodstuffs shall be regulated with reference to the content of the basic chemical contaminants that are hazardous for human health.

The hygienic requirements in reference to the permissible level of toxic element content shall be imposed on all kinds of foodstuff raw materials and foodstuffs.
- 3.9 The content of the myco-toxins – aflatoxin B1, desoxinivalenol (vomitoxin), zearalenol, T-2 toxin, patulin- is limited in the foodstuff raw materials and foodstuffs of the plant origin, aflatoxin M1 is limited in milk and dairy produce. The priority contaminants are desoxinivalenol for the grain products; aflatoxin B1 for nuts and seeds of oil containing plants; patulin for fruit and vegetables.
- 3.10 Myco-toxin presence is not allowed in children's and dietary products.
- 3.11 All kinds of foodstuffs are regulated with reference to pesticides: hexachlorine-cyclohexan (α, β, γ -isomers), DDT and its metabolites. Grain and products of its processing are regulated also with respect to the mercury-organic pesticides, 2,4-D acid, its salts and esters. Fish and products of its processing are regulated also with respect to 2,4-D acid, its salts and esters.
- 3.12 Foodstuff raw materials and foodstuffs are controlled with respect to the residue levels of pesticides and agricultural chemicals, including fumigants in accordance with the information submitted by the manufacturer (supplier) of the product on the pesticides and agricultural chemicals used for its production and storage.
- 3.13 The sanitary epidemiological evaluation of foodstuff raw materials and foodstuffs that contain pesticides is conducted in accordance with the effective hygienic regulations with respect to the environmental pesticide content.
- 3.14 Animal origin foodstuffs are regulated in reference to the residual quantities of animal growth stimulants (including hormone preparations), medical drugs (including antibiotics) used in animal husbandry for animal and poultry feeding, treating for diseases and disease prophylactics.

Meat, meat produce, by-products of slaughtered cattle and poultry is subject to regulation for both feed antibiotics approved for application in agriculture – grizyn, bacitracine, and curative antibiotics most frequently used in veterinary practices – tetracycline antibiotics, levomitsetin. Milk and dairy products shall be regulated for penicillin, streptomycin, tetracycline group antibiotics, levomitsetin; eggs and egg produce – bacitracine, tetracycline group antibiotics, levomitsetin.
- 3.15 Animal growth stimulant content (including hormone preparations), medical drugs (including antibiotics) used in animal husbandry for animal and poultry feeding, treating for diseases and disease prophylactics, preparations not mentioned in section 3.14 are regulated with respect to the information submitted by the manufacturer (supplier) of the product pertaining to the animal growth stimulants and medical drugs used for its manufacture and storage.
- 3.16 Polychlorinated biphenyles are regulated in fish and fish products; benzapyrene is regulated in grain,

smoked meat and fish products.

- 3.17 Benzopyrene is not permitted in children's and dietary foodstuffs.
- 3.18 Specific foodstuffs are regulated for: nitrogen-containing substances: histamine – in fish belonging to the salmon and mackerel families (including the tuna fish group); nitrates – in fruit and vegetable products; N-nitrozamines – in fish and fish products, meat products and brewer's malt.
- 3.19 Fatty products are regulated for oxidative deterioration indices; an acid number and a peroxide number.
- 3.20 Foodstuffs are regulated for the hygienic standards of radionuclide content.

Radiation safety of foodstuffs is determined by compliance with the permissible level of specific activity for radionuclides of cesium-137 and strontium-90 established in the current Sanitary Rules. A food product is monitored with the help of the compliance number – B, to determine its compliance with the radiation safety criteria. This number is calculated by measuring the specific activity of cesium-137 and strontium-90 in a sample:

$B = (A/H) 90\text{Sr} + 137\text{Sr}$, where A is the calculated number of the 90Sr and 137Sr specific activity in a foodstuff (Bk/kg); H – the tolerable level of the specific activity for 90Sr and 137 Sr in the same foodstuff (Bk/kg).

Radiation safety of a food product contaminated with other radionuclides is determined by its compliance with the Sanitary Rules with respect to the radiation safety standards.

- 3.21 Food products shall not contain pathogenic microorganisms and parasitic disease agents, nor their toxins causing infectious and parasitic diseases, or posing a threat to human and animal health.
- 3.22 The sanitary epidemiological evaluation of meat and meat products, fish, crustacean, mollusks, amphibians, reptiles, and products processed from them with reference to parasitic disease agents regulated by the Sanitary Rules pertaining to parasitologic control procedures, and parasitologic safety parameters (Attachment 6).
- 3.23 Parasitic disease agents like cyclicercus, trichinella and echinococcus larvae, sarcocystis and toxoplasma cysts are not permitted in meat and meat products.
- 3.24 Live larvae of helminthes dangerous for human health are not permitted in fish, crustacean, mollusks, amphibian, reptile and products produced from them.
- In the event live larvae are detected, reference shall be made to the Sanitary Rules for parasitic disease prophylactics.
- 3.25 Eggs of helminthes and cysts of coli protozoa are not permitted in fresh and freshly frozen table greens, vegetables, fruit and berries.
- 3.26 Hygienic standards in reference to the parasitological parameters of potable water safety are determined in accordance with the hygienic standards set for water quality in the centralized systems of potable water supply.
- 3.27 Hygienic standards for the microbiological parameters of foods safety and nutrition include the following groups of microorganisms:
- sanitary-indicative ones that include the quantity of mesophyll aerobic and optional-anaerobic microorganisms (QMA&OAMO) as well as Escherichia coli group bacteria – CGB (coli-forms), Enterobacteriaceae family bacteria, enterococcus;
 - conditionally pathogenic microorganisms that include *E.coli*, *S. aureus*, *Proteus* type bacteria, *B.cereus* and sulphitreducing clostridia, *Vibrio parahaemolyticus*;
 - pathogenic microorganisms including salmonella and *Listeria monocytogenes*, *Yersinia* type bacteria;

- decay microorganisms like yeast and molds, milk-sour microorganisms;
 - fermentation micro-flora microorganisms and probiotic microorganisms (milk-sour microorganisms, propionic-sour microorganisms, yeast, bifidobacteria, acidophilic bacteria and others) in products with regulated levels of biotechnical flora, and in probiotic products.
- 3.28 Foodstuff regulation in reference to the safety of microbiological parameters is carried out with respect to the majority of micro-organic groups based on the alternative principle, i.e. the subject for regulating is the produce mass where *E. coli* group bacteria, the majority of conditionally pathogenic microorganisms as well as pathogenic microorganisms including salmonella and *Listeria monocytogenes* are not permitted. In some other instances the standard reflects the quantity of colony-forming units in 1 gram (ml) of the product (QCFU/G, ml).
- 3.29 Safety criteria for canned foodstuffs (industrial sterility) is zero microorganisms that are capable of developing under the storage temperature set for storing the specific type of canned food, as well as zero microorganisms and microbial toxins dangerous to human health in the canned product (Attachment 8).
- 3.30 Biologically active additives to food are the source of food, minor, pro- and prebiotic natural (identical to natural) biologically active substances (components) of food that ensure they get into the human organism when being consumed with food or included in the foodstuff composition. Biologically active substances, food components, and products that are the source of them, used to manufacture biologically active additives to food shall be effective and shall not bring any harm to human health (Attachment 5a).
Biologically active substances, food components, and products that are the source of them, which in accordance with modern scientific research data are dangerous to human life and health when used as part of biologically active additives to food, are not permitted for use to manufacture biologically active additives to food (Attachment 5b).
- 3.31 Nutrition indices are determined for foodstuffs. The nutrition indices are substantiated by the producer (developer of the technical documentation) based on the analytical research methods and/or with the help of a method of calculation, which takes into account the foodstuff recipe and information about raw material composition.
- 3.32 Certain foodstuffs in reference to their nutrition shall meet the requirements of these Sanitary Rules (Attachment 2)
- 3.33 Foodstuffs for children's consumption shall comply with the needs of the functional state of the child's organism taking into consideration his/her age, and contain no danger to the child's health.
- 3.34 Foodstuffs for children's consumption and their components, foodstuffs for pregnant and nursing women (hereinafter referred to as specialized products) shall comply with the hygienic criteria for the safety and nutrition established by these Sanitary Rules (Attachment 3).
- 3.35 Food additives that in accordance with the modern scientific research data do not bring any harm to human life and health and the life and health of the future generations are permitted for use in foodstuffs (Attachment 7).
Foodstuffs containing food additives that are not enlisted in Attachment 7 are not eligible for production, importation and sale on the territory of the Russian Federation. Their disposal or elimination shall be accomplished in accordance with approved procedures.
- 3.36 The terms for food additives application as well as their permissible levels in foodstuffs are regulated in the Sanitary Rules for food additives application.